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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,703	02/20/2002	Craig Anderson	1/1282	7672
28501	7590	01/07/2004	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION			SPIVACK, PHYLLIS G	
900 RIDGEBURY ROAD			ART UNIT	
P. O. BOX 368			PAPER NUMBER	
RIDGEFIELD, CT 06877			1614	

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/079,703

Applicant(s)

ANDERSON ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

An Amendment filed October 24, 2003 is acknowledged. Claims 2, 3, 7, 9 and 10 are canceled. Claims 1, 4-6 and 8 remain under consideration.

An Information Disclosure Statement filed December 5, 2003 is further acknowledged and has been reviewed.

Subsequent to the cancellation of claims 9-10 and the amendment to claim 8, wherein the claim has been rewritten as a method of use claim, the rejections of record in the last Office Action under 35 U.S.C. 112, second paragraph, 35 U.S.C. 101 and 35 U.S.C. 102(a) are moot.

In the last Office Action claims 1-10 were rejected under 35 U.S.C. 103 as being unpatentable over Mihm et al., U.S. Patent 5,565,469.

The rejection is withdrawn because telmisartan possesses a carboxy group as the substituent of R₄ (not formyl) and is out of the scope of the compounds encompassed in Mihm's formula I.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Tamura, M., US 2003/0083339, and Flood et al., European Journal of Pharmacology (abstract).

Tamura teaches the administration of angiotensin II antagonists in enhancing cognitive performance and in treating cognitive disorders. See page 11, section [0126].

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Further, telmisartan is disclosed as a representative Ang II receptor antagonist on page 9, section [0100]. Flood teaches the administration of the ACE inhibitor ramipril to enhance memory retention. Motivation to administer both compounds flows from the efficacy demonstrated in the prior art wherein a synergistic effect is achieved. Further, one having ordinary skill in the neurology art would have been motivated to administer ramipril and telmisartan together for the treatment of dementia and/or regression of cognitive function because each compound has been previously administered for the same therapeutic endpoints. In the absence of evidence to the contrary, it is generally *prima facie* obvious to use in combination two or more agents that have previously been used separately for the same purpose. In re Kerkhoven 205 USPQ 1069 (CCPA).

Obviousness does not require absolute predictability but only the reasonable expectation of success. See In re O'Farrell, 7 USPQ 2d 1673.

Specific statements in the references that would spell out the claimed invention are not necessary to show obviousness since questions of obviousness involve not only what references expressly teach, but also what they would collectively suggest to one skilled in the art. See In re Burckel 201 USPQ 67 (CCPA).

The selection of optimal concentrations of telmisartan and ramipril are parameters well within the purview of those skilled in the art through no more than routine experimentation.

Thus the claims are denied.

Applicants' amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Phyllis G.

Spivack at telephone number 703-308-4703.



Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

January 5, 2004